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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/073,960      | 02/14/2002  | Leonid Metzger       | 1662/56202          | 8710             |

26646 7590 12/20/2002

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EXAMINER

BERNHARDT, EMILY B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/073,960

Applicant(s)

METZGER et al.

Examiner

Emily Bernhardt

Art Unit

1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 & 6 6) ☐ Other:

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Claims 1-6,17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.It is not seen how claims 1-6 materially differ in scope from one another and thus appear to be substantial duplicates. The specification does not make any distinctions as to difference in purity levels for the characterization data in dependent claims 2-6 . Thus the difference in scope is unclear.

2.Main claim 17 as recited is not completely describing the invention since reaction conditions are not set forth much less additional reactant(s) needed to make final product- i.e. anhydrous form of mirtazapine. It is suggested the steps of 18 and 19 be incorporated into claim 17.

3. Organic “liquid” in main claim 7 and claims dependent thereon should be clarified in accord with its sole use in the specification as the solvent rather than a reactant.

Claims 7-10,13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those solvents recited on p.4, top paragraph of the specification , does not reasonably provide enablement for any and

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all “organic liquids” embraced in the claims . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. Specification provides no additional guidelines as to what constitutes suitable solvents for the preparation of the precursor carboxylate salt form and there is no basis in the prior art, Ishii and van der Burg, who rely on particular solvents to make the same salt.

The art of record provided by applicants has been noted and while similar to that claimed herein provides no teaching or suggestion to prepare any hydrated forms of carboxylate salt claimed herein. Ishii in particular while employing the salt form for the next step to making mirtazapine directly employs reductive conditions in a basic media.

**Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.**

**A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.**

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*Emily Bernhardt*

**EMILY BERNHARDT**

**PRIMARY EXAMINER**

**GROUP 1600**